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10/598,987	09/18/2006	Alexander Thomas Jacobs	X16922	3012
25885 7590 01/09/2008 ELI LILLY & COMPANY PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, IN 46206-6288				
EXAMINER CARPENTER, WILLIAM R				
ART UNIT		PAPER NUMBER		
4111				
NOTIFICATION DATE		DELIVERY MODE		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

### Office Action Summary

**Application No.**

10/598,987

**Applicant(s)**

JACOBS ET AL.

**Examiner**

William Carpenter

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 September 2006.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-4, 10 and 11 is/are rejected.  
7) ☒ Claim(s) 5-9 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/5508)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Specification***

1. The disclosure is objected to because of the following informalities: Page 4, Line 28 contains an empty space " \_\_\_\_\_ " which is believed to be reserved as a place holder for the application number of an associated WIPO application.

Appropriate correction is required.

### ***Claim Objections***

2. Claim 5 is objected to because of the following informalities:

Claim 5 makes reference to a "gear set carrier"; however the use of this term appears to be improper because it does not appear to have positive antecedent basis in the specification. It is not clear what Applicant considers to be the "gear set carrier". For the sake of prosecution it was assumed that the "gear set carrier" referred to the "pinion-engaging piece (62)". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 5 makes reference to a "means for driving" or "driving means" as part of the medication dispensing apparatus, thereby invoking 112 6<sup>th</sup> paragraph. However, it is not clear from the specification what part or parts of the device Applicant considers to be the "driving means". Applicant briefly discloses the "driving means" in the specification (Page 2: Lines 10, 16, and 20), but fails to indicate any specific structure or reference numerals for what Applicant considers to be the "driving means". Claim 5 does appear indicate that the "gear set carrier" is part of the "driving means" stating "a gear set carrier of said driving means". However, as per the above objection to Claim 5 it is unclear what element Applicant considers to be the "gear set carrier". For the sake of prosecution the drive means was taken to describe a combination of the gear set (52), the pinion-engaging piece (62), and the plunger element (90). Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

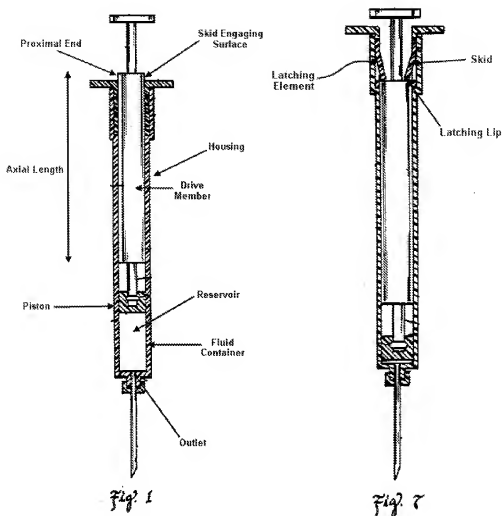
6. Claims 1, 2, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,114,405 ("Winter")

As regards to Claim 1, Winter discloses a medication dispensing apparatus (Figures 1 and 7) comprising a housing and a drive member within said housing and movable in a distal direction (Figures 1 and 7 in series). Winter also discloses a fluid container defining a medicine-filled reservoir with a movable piston at one end and an outlet at the other end. Winter further discloses that the piston is engageable by the drive member as to be advanced towards the outlet a distance equal to a distal movement of the drive member (Figures 1 and 7 in series). Additionally, Winter discloses a means for driving the drive member distally. While the language of the limitation appears to invoke § 112 6<sup>th</sup> Paragraph, it is not clear what Applicant considers to be the "driving means". As per the above § 112 2<sup>nd</sup> Paragraph rejection of Claims 1 and 2, the "driving means" is being interpreted as a combination of items (52), (62), and (90). In the instant case the driving means of Winter is believed to be an equivalent to the "driving means" of Applicant since both structures work to drive the drive member in the distal direction.

Winter further discloses a latching element comprising a latching lip and a skid, wherein the drive member includes an axially extending, skid-engaging surface along which the skid is slidable (Figures 1 and 7 in series) as the drive member passes distally during advancement. Winter discloses the skid-engaging to have an axial length and a proximal end, wherein the axial length is structured and arranged with the skid so as to maintain the latching lip against a spring force in a first position free of said driving

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means during dose preparing and injection prior to a final dose administration (Column 2, Lines 19-24). Winter discloses that the skid-engaging surface shifts distally such that the skid passes beyond the proximal end upon administration of the final dose (Figure 7) and whereby the latching lip is urged from a first position (Figure 1) to a second position (Figure 7) to physically lock the driving means and prevent further dose preparing and injecting. In the instant case, though indirect, the locking mechanism of the device of Winter is believed to physically lock the driving means by preventing proximal movement of the drive member and associated driving means, while the plunger abutting the end of the housing prevents movement of the drive member and associated driving means in the distal direction, thereby physically locking the driving means.



As regards to Claim 2, the proximal end of the skid-engaging surface coincides with the proximal end of the drive means (Figure 1).

As regards to Claim 10, Winter teaches the skid-engaging surface to be smooth (Figure 1).

7. Claims 1 and 2 are rejected under 35 U.S.C. 102 (a), (b), or (e) as being anticipated by WIPO Publication 2003/080160 ("Judson et al.")

While the reference of Judson et al. fails to predate Applicant's earliest effective filing date by more than one year i.e. 60/557,545 (03/30/2004), this provisional

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application does not appear to show full support for the invention of Claim 1. Should Applicant be able to show specific support for the invention in provisional application 60/557,545 Judson et al. is still made available under §102 (a) and (e).

As regards to Claim 1, Judson et al. discloses a medication dispensing apparatus (38) having a housing (20) and a drive member (62) disposed within the housing and movable in the distal direction (Paragraph 7). Judson et al. further discloses a fluid container (48) defining a medicine filled reservoir (50) with a movable piston (52) at one end and an outlet (43) at the other. Judson et al. discloses that the piston is engaged by the drive member and advanced distally towards the outlet as to expel the medication (Paragraph 8). Additionally, Judson et al. teaches a means for driving the drive member in the distal direction in the form of a gear set (64) and plunger (66) in combination. In the instant case the language of Applicant's limitation "means for driving said drive member distally" appears to invoke § 112 6<sup>th</sup> Paragraph, which was interpreted as per the above § 112 2<sup>nd</sup> Paragraph rejection assumed to refer to a combination of the gear set (52), the pinion-engaging piece (62), and the plunger element (90). The combination of the gear set (64) and plunger (66) of Judson et al. is believed to be an equivalent of the "driving means" of Applicant.

Judson et al. additionally teaches a latching element (74) including a skid/pawl (The body of Item 74) and a latching lip (The distal tip of Item 74). Judson et al. discloses this skid to slide, or skid, along an axially extending, skid-engaging surface (78) disposed upon the drive member. While not explicitly disclosed by Judson et al., the skid-engaging surface has a distal end (Denoted by the ratcheted tooth nearest the



piston engaging surface) and a proximal end (Denoted by the final ratcheted tooth farthest from the piston engaging surface). While Judson et al. does not explicitly disclose it, the latching lip of the latching element is held against a spring force, created through a combination of the skids disclosed resiliency (Paragraph 53) and the normal force supplied by the skid-engaging surface (Figure 3), in a first position that is free of the driving means during dose preparation and injecting.

Judson et al. teaches that as the drive member advances the skid traverses along its length, of which the skid-engaging surface continues nearly its entire length (Paragraph 53). It is presumed that when the device delivers its final dose the drive member will be fully distally disposed such that the body of the skid has passed the proximal end (Denoted by the final ratchet tooth) and the latching lip engages the final ratchet tooth to prevent backwards movement. The spring force created by the normal force supplied to the resilient skid by the skid-engaging surface allows the latching lip to move up and down as to traverse the ratchet teeth and move from a first position (Figure 3) to a second position (Not shown, denoted by latching lip abutting the final ratchet tooth). The skid prevents proximal movement of the drive member, which in combination with the ending of the track (80) and the flanged end (82), physically locks the driving means (62) in relation to the drive member, thereby preventing further dose preparation and injecting (Paragraph 9).

As regards to Claim 2, Judson et al. discloses that the proximal end of the skid-engaging surface comprises a proximal end of the drive member (Figure 2). While the skid-engaging surface is not disclosed as extending the entirety of the drive member up

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to its most proximal surface this is not believed to be necessary to satisfy the conditions of "a proximal end". All that is believed to be necessary is that the skid-engaging surface be disposed appreciably near the most proximal surface, in the region that may be reasonably conveyed as "a proximal end".

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 3 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,114,405 ("Winter") as applied to Claim 1 above, and further in view of Australian Patent No. 2002100005 ("Poljansek").

As regards to Claim 3, Winter fails to disclose that the skid is disposed distally of the latching lip, instead teaching that the skid is proximal of the latching lip. However, the position of the skid relative to the latching lip is believed to be an obvious variant as

seen in Poljansek. Poljansek teaches a latching element comprising a skid and a latching lip (1), wherein the latching lip is proximal to the skid (Figure 2A). Poljansek teaches forming a notch (2) in the drive member to engage the latching element (Figure 2A). It would have been obvious to orient the latching element of White such that the latching lip is proximal to the skid, as taught by Poljansek, as both configurations result in the formation of a valid latching mechanism.

As regards to Claim 11, as disclosed above it would have been obvious for one having ordinary skill in the art to modify the latching element of Winter such that the skid is disposed distally of the latching lip while adding a corresponding latchable element in the form of a notch, as is taught by Poljansek. Given this obvious configuration, the latching element which comprises the rim of the skid along an opening (Denoted by the empty space caused by the distal displacement of the drive member relative the housing) would interact with the notch form in the driving means, as per the teachings of Poljansek.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,114,405 ("Winter") as applied to Claim 1 above, and further in view of Australian Patent No. 2002100005 ("Poljansek") and US Patent No. 6,979,316 ("Rubin et al.")

As regards to Claim 4, as per the above rejection in regards to Claim 3, it would have been obvious for one having ordinary skill in the art to modify the device of Winter by orienting the latching element such that the skid is disposed distal to the latching lip, while adding a notch disposed on the driving means to correspond to this new

configuration. While Winter and Poljansek both disclose the skid of the latching element to comprise a blade shape member, they fail to teach that the latching lip comprises a transversely extending flange. However, the use of latching lip comprising a transversely extending flange is well known in conjunction with a notched latching engagement in injection devices. For example Rubin et al. discloses a non-reusable injection device (18) having a latching element comprising a skid (50) in conjunction with a transversely extending latching lip (68) that corresponds to a notch (51) as to securely lock the drive member (32) in place relative the housing (62). It would have been obvious for one having ordinary skill in the art to form the latching lip of the modified device of Winter as a transversely extending flange in order to provide a more secure engagement with the corresponding notched latching engagement.

#### ***Allowable Subject Matter***

8. Claims 5-9 are objected to as being dependent upon a rejected base claim, but may be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, as well as correcting the raised claim objections and rejections under § 112 2<sup>nd</sup> Paragraph.

As regards to Claim 5, Winter fails to teach a gear set in conjunction with the disclosed injection device, therefore there is certainly no element that could be properly interpreted as a "gear set carrier". While the use of gear sets is well known in the art of injection devices and it would have been obvious to include such a gear set to the device of Winter it is not clear how one having ordinary skill in the art could modify the

device such that latching lip engages a latchable element disposed on the carrier of the added gear set. Additionally, Judson et al. fails to disclose that the latching lip of the latching element engages a latchable element disposed on a gear set carrier. While latching elements that correspond to a latchable element disposed on a gear set carrier are well known, for example US Patent No. 5,501,124 ("Ashby"). However, these device have an appreciably different mode of function from the device of Judson et al. and it is not clear how one having ordinary skill in the art would modify the device of Judson et al. as to provide a latching element that meets the limitations of the independent Claim 1 as well as the limitations of Claim 5. Therefore Claims 5-9 may contain allowable subject matter.

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM CARPENTER whose telephone number is (571)270-3637. The examiner can normally be reached on Monday through Thursday from 7:30AM-5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sam Yao can be reached on 571-272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

WC  
1/3/2008

/Sam Chuan C. Yao/

Supervisory Patent Examiner, Art Unit 4111